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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 26, 2000, 8:30 a.m. to 5:30 p.m.

Location: 5630 Fishers Lane, Center for Drug Evaluation and Research Advisory Committee conference room 1066, Rockville, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: TOPPERK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss specific scientific issues where the additional expertise of the subcommittee is needed to aid the agency in refining draft guidances for orally inhaled and nasal drug products in the areas of: (1) Chemistry, manufacturing, and controls; and (2) in vitro and in vivo bioavailability/bioequivalence.

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Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 19, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 19, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated:

March 14, 2000

Linda A. Suydam ()

Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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